Paper No. 51

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ISABELLE RIVIERE, LAWRENCE K. COHEN, BRAD GUILD, LORI F. RAFIELD, PAUL ROBBINS and RICHARD C. MULLIGAN

Appeal No. 2001-1838
Application No. 08/252,710

HEARD: May 21, 2002

Before WINTERS, ADAMS, and GRIMES, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 1 through 4, 6 through 31, 35 through 37 and 42 through 44. Claims 38 through 41, which are the only other claims remaining in the application, stand allowed.

REPRESENTATIVE CLAIMS

Claims 1 and 44, which are illustrative of the subject matter on appeal, read as follows:

1. A recombinant retroviral vector useful to nonselectively transduce cells, comprising:

(a) a 5' LTR derived from a retrovirus of interest;
(b) a splice donor site located 3' to said 5' LTR;
(c) a Psi packaging site located 3' to said splice donor site;
(d) a consensus splice acceptor site located 3' to said Psi packaging site;
(e) an insertion site for a gene of interest located 3' to said consensus splice acceptor site;
(f) a 3' LTR derived from a retrovirus of interest located 3' to said insertion site; and

wherein said vector does not contain a complete selectable marker gene used for the transduction of said cells, or a complete gag, env, or pol gene between said 5' and 3' LTR [emphasis added].

44. A recombinant retroviral vector useful to nonselectively transfect cells, comprising:

(g) a 5' LTR derived from retrovirus of interest;
(h) a splice donor site located 3' to said 5' LTR;
(i) a Psi packaging site located 3' to said splice donor site;
(j) a consensus splice acceptor site, derived from MOV-9, located 3' to said Psi packaging site;
(k) an insertion site for a gene of interest located 3' to said consensus splice acceptor site;
(l) a 3' LTR derived from a retrovirus of interest located 3' to said insertion site; and

wherein said vector does not contain a complete selectable marker gene used for the tranfection of said cells, or a complete gag, env, or pol gene between said 5' and 3' LTR [emphasis added].

THE REJECTION

In rejecting all of the appealed claims, the examiner does not rely on any prior art references. Claims 1 through 4, 6 through 31, 35 through 37, and 42 through 44 stand rejected under 35 U.S.C. § 112, first paragraph, as containing a limitation, added by amendment, which does not enjoy adequate written descriptive support in the specification as filed.

DELIBERATIONS

Our deliberations in this matter have included evaluation and review of the following materials:

(1) the instant specification, including figures 1 through 17 and all of the claims on appeal;

(2) applicants' main Brief (Paper No. 42) and the Reply Brief (Paper No. 45); and

(3) the Examiner's Answer (Paper No. 44).

On consideration of the record, including the above-listed materials, we reverse the examiner's rejection under 35 U.S.C. § 112, first paragraph.

DISCUSSION

The examiner argues that the terms "a consensus splice acceptor site" and "a consensus splice acceptor site, derived from MOV-9" lack adequate, written descriptive support in the specification, as filed. In our judgment, however, the examiner has not satisfied the PTO's initial burden of producing a factual basis for this rejection. That is, the examiner has not established a prima facie case that applicants fail to comply with the written description requirement of 35 U.S.C. § 112, first paragraph.

Focusing on applicants' specific splice acceptor site described in the specification, paragraph bridging pages 28 and 29, the examiner argues that "a consensus splice acceptor site" is a broad term "not supported by the narrower disclosure of the specification" (Paper No. 44, page 4, line 1). The examiner argues that applicants' specification "does not support the broader 'consensus' language,"

which was introduced by amendment and appears in the appealed claims (Paper No. 44, page 6, line 7). We disagree with this reasoning.

The examiner's position to the contrary, notwithstanding, the term "consensus" is a limitation serving to further restrict the meaning of "a splice acceptor site" described in the original specification. This much is clear from a review of the prosecution history, where the term "consensus" was added as a claim limitation to distinguish over prior art (Paper No. 27).

We believe that the examiner erred by not adequately evaluating the specification in its entirety, including the generic description of a splice acceptor site ("the vector preferably contains a splice donor site and a splice acceptor site, wherein the splice acceptor site is located upstream from the site where the gene of interest is inserted." Original specification, sentence bridging pages 6 and 7). Any person skilled in the art would recognize, and it is undisputed by the examiner, that "a splice acceptor site" embraces a limited number and type of nucleic acid sequences. These include a consensus splice acceptor site, i.e., the consensus sequences most commonly occurring in nature (see page 94 of Recombinant DNA, A Short Course, Watson, et al., Scientific American Books (1983), copy attached to the Appeal Brief); and a non-consensus splice acceptor site.[1]

Armed with the description of "a splice acceptor site," any person skilled in the art would immediately envision the consensus sequences most commonly occurring in nature; these are the everyday, routine, quotidian sequences. Although the limitation "a

[1] To the extent that the examiner would argue that alternative splice consensus sequences also fall within the generic description of "a splice acceptor site," any person skilled in the art would recognize that those sequences are not the consensus sequences most commonly occurring in nature.

consensus splice acceptor site" is not described in haec verba in the original specification, nonetheless, we believe that the specification provides implicit support for that limitation. By its very nature, the consensus splice acceptor site would recommend itself to any person skilled in the art upon review of the specification as filed.

By definition, a consensus splice acceptor site is a typical splice acceptor site. Logically, a description showing possession of a recombinant retroviral vector containing a splice acceptor site also shows possession of that vector containing a typical splice acceptor site, viz., a consensus splice acceptor site.

With respect to claim 44, we think it clear that component (j) of that claim is limited to the MOV-9 splice acceptor site. See the specification, paragraph bridging pages 28 and 29.

For these reasons, we hold that the examiner has not established a prima facie case that applicants fail to comply with the written description requirement of 35 U.S.C. § 112, first paragraph. Accordingly, the examiner's decision rejecting claims 1 through 4, 6 through 31, 35 through 37, and 42 through 44 is reversed.

REVERSED

Sherman D. Winters
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

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ELD

Anne-Louise Kerner, PhD
Hale and Dorr, LLP Americas
60 State Street
Boston, MA 02109-2711